



## General

### Guideline Title

Clinical practice guideline: allergic rhinitis.

### Bibliographic Source(s)

Seidman MD, Gurgel RK, Lin SY, Schwartz SR, Baroody FM, Bonner JR, Dawson DE, Dykewicz MS, Hackell JM, Han JK, Ishman SL, Krouse HJ, Malekzadeh S, Mims JW, Omole FS, Reddy WD, Wallace DV, Walsh SA, Warren BE, Wilson MN, Nnacheta LC. Clinical practice guideline: allergic rhinitis. *Otolaryngol Head Neck Surg*. 2015 Feb;152(1 Suppl):S1-S43. [364 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Regulatory Alert

### FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [December 14, 2016 – General anesthetic and sedation drugs](#) : The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.

## Recommendations

### Major Recommendations

The evidence grades (A-D, X) and evidence-based statements (Strong Recommendation, Recommendation, Option, and No Recommendation) are defined at the end of the "Major Recommendations" field.

## Statement 1. Patient History and Physical Examination

Clinicians should make the clinical diagnosis of allergic rhinitis (AR) when patients present with a history and physical examination consistent with an allergic cause and 1 or more of the following symptoms: nasal congestion, runny nose, itchy nose, or sneezing. Findings of AR consistent with an allergic cause include, but are not limited to, clear rhinorrhea, nasal congestion, pale discoloration of the nasal mucosa, and red and watery eyes.

*Recommendation based on observational studies, with a preponderance of benefit over harm.*

### Action Statement Profile

- Quality improvement opportunity: To promote a consistent and systematic approach to initial evaluation of the patient with AR
- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in evidence: High
- Benefits: Avoid unnecessary treatment or testing, time referrals appropriately, institute a specific therapy, improve quality of life and productivity, improve accurate diagnosis
- Risks, harms, costs: Inappropriate treatment, potential misdiagnosis from using history and physical alone
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Although the Guideline Development Group recognized that a conclusive diagnosis of AR is difficult without diagnostic testing, making a presumptive diagnosis of AR based on history and physical examination alone is reasonable.
- Intentional vagueness: The use of the words "clinical diagnosis" acknowledges that this is a presumptive diagnosis not confirmed with testing. The use of the words "when patients present with a history and physical examination consistent with an allergic cause" assumes that a clinician will know how to make an appropriate diagnosis of AR. Specifics of what constitutes a history and physical examination consistent with an allergic cause are provided in the supporting text in the original guideline document.
- Role of patient preferences: Limited—Patient may request that additional testing be conducted before deciding on initiation of treatment.
- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

## Statement 2. Allergy Testing

Clinicians should perform and interpret, or refer to a clinician who can perform and interpret, specific immunoglobulin E (IgE) (skin or blood) allergy testing for patients with a clinical diagnosis of AR who do not respond to empiric treatment, or when the diagnosis is uncertain, or when knowledge of the specific causative allergen is needed to target therapy.

*Recommendation based on randomized controlled trials (RCTs) and systematic reviews, with a preponderance of benefit over harm.*

### Action Statement Profile

- Quality improvement opportunity: Improve accurate diagnosis and avoid unnecessary testing
- Aggregate evidence quality: Grade B, based on randomized controlled trials and systematic reviews
- Level of confidence in evidence: High
- Benefits: Confirming diagnosis, directing pharmacologic therapy, directing immunotherapy, avoidance strategies, avoidance of ineffective therapy, reduce cost of unnecessary testing
- Risks, harms, costs: Cost of testing, adverse events from testing, misinterpretation of results, inaccurate test results (false positives and negatives)
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Patients may benefit from identification of specific allergic cause.
- Intentional vagueness: The Guideline Development Group did not specify which specific IgE test (blood or skin) to order. The Guideline Development Group also did not specify which allergens to test, as that was beyond the scope of this guideline. They did not specify what constitutes empiric treatment, although this is generally treatment that is initiated prior to confirmatory, IgE-specific testing and could include recommending environmental controls, allergen avoidance, or medical management. Lack of response to empiric treatment is not defined to allow the clinician to exercise judgment in making this determination but is generally thought to include patients with persistent symptoms despite therapy.
- Role of patient preferences: Moderate—Shared decision making in discussion of harms and benefits of testing; clinicians and patients should discuss potential costs, benefits, and adverse effects of additional testing, and type of testing, either skin or blood, if neither is contraindicated.
- Exclusions: None

- Policy level: Recommendation
- Differences of opinion: None

### Statement 3. Imaging

Clinicians should not routinely perform sinonasal imaging in patients presenting with symptoms consistent with a diagnosis of AR.

*Recommendation against based on observational studies, with a preponderance of benefit over harm.*

#### *Action Statement Profile*

- Quality improvement opportunity: Reduction of variation of care, reduction of potential harm from unnecessary radiation exposure
- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in evidence: High
- Benefits: Avoiding unnecessary radiation exposure, reduction of cost, reducing variation in care
- Risks, harms, costs: Inaccurate or missed diagnosis of pathology with similar presenting symptoms
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: The word *routine* was used to allow for circumstances where the patient history may warrant imaging for evaluation of another problem besides AR
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinions: None

### Statement 4. Environmental Factors

Clinicians may advise avoidance of known allergens or may advise environmental controls (e.g., removal of pets; the use of air filtration systems, bed covers, and acaricides [chemical agents that kill dust mites]) in AR patients who have identified allergens that correlate with clinical symptoms.

*Option based on RCTs with minor limitations and observational studies, with equilibrium of benefit and harm.*

#### *Action Statement Profile*

- Quality improvement opportunity: Reduce expenditures on environmental measures that do not improve symptoms
- Aggregate evidence quality: Grade B, based on RCTs with minor limitations and observational studies
- Level of confidence in evidence: Moderate—with the exception of studies on house dust mites, the majority of the studies were small
- Benefits: Decreased allergen levels and possible reduction in symptoms
- Risks, harms, costs: Cost of environmental controls, emotional effect (e.g., recommending animal avoidance in pet lovers), cost of ineffective recommendation
- Benefit-harm assessment: Equilibrium
- Value judgments: Many studies have demonstrated a reduction in allergen levels with environmental controls; however, benefits in alleviating symptoms are limited. Use of multiple avoidance techniques may be more effective than individual measures.
- Intentional vagueness: None
- Role of patient preferences: Large—Shared decision making in discussion of evidence for effectiveness of possible controls and the need to weigh the costs and benefits
- Exclusions: None
- Policy level: Option
- Difference of opinion: None

### Statement 5. Chronic Conditions and Comorbidities

Clinicians should assess patients with a clinical diagnosis of AR for, and document in the medical record, the presence of associated conditions such as asthma, atopic dermatitis, sleep-disordered breathing, conjunctivitis, rhinosinusitis, and otitis media.

*Recommendation based on randomized trials with some heterogeneity and a preponderance of benefit over harm.*

#### *Action Statement Profile*

- Quality improvement opportunity: Identification of significant comorbid conditions or complications, potential for treatment optimization

- Aggregate evidence quality: Grade B, based on randomized trials with some heterogeneity
- Level of confidence in the evidence: High
- Benefits: Increased awareness of these conditions; identification of treatable conditions; knowledge of these conditions may alter recommendations for AR treatment as comorbid conditions can alter response to treatment.
- Risks, harms, costs: Potential erroneous diagnosis of comorbid conditions
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

#### Statement 6. Topical Steroids

Clinicians should recommend intranasal steroids for patients with a clinical diagnosis of AR whose symptoms affect their quality of life.

*Strong recommendation based on RCTs with minor limitations and a preponderance of benefit over harm.*

#### Action Statement Profile

- Quality improvement opportunity: Optimizing the use of proven effective therapy
- Aggregate evidence quality: Grade A, based on RCTs with minor limitations
- Level of confidence in the evidence: High
- Benefits: Improved symptom control, improved quality of life, better sleep, potential cost saving with monotherapy, targeted local effect
- Risks, harms, costs: Topical side effects, epistaxis, drug side effects, potential growth concerns in children, septal perforation, and the cost of medication
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Large—There are multiple classes of effective therapy with differing risks, adverse effects, costs, and benefits. The clinician should use his or her expertise in assisting patients to evaluate the best treatment and to ensure patient compliance.
- Exclusions: None
- Policy level: Strong recommendation
- Differences of opinions: Minor. There were some differences of opinion regarding the best therapy for mild or intermittent symptoms, as oral or nasal antihistamines may be adequate therapy for those patients.

#### Statement 7. Oral Antihistamines

Clinicians should recommend oral second-generation/less sedating antihistamines for patients with AR and primary complaints of sneezing and itching.

*Strong recommendation based on RCTs with minor limitations and a preponderance of benefit over harm.*

#### Action Statement Profile

- Quality improvement opportunity: Avoidance of sedating antihistamine use and promotion of use of effective symptom-directed therapy
- Aggregate evidence quality: Grade A, based on RCTs with minor limitations
- Level of confidence in evidence: High
- Benefits: Rapid onset of action, oral administration, relief of symptoms, over-the-counter availability, potential cost saving (generic brand), relief of eye symptoms
- Risks, harms, costs: Systemic side effects (sedation), dry eyes, urinary retention
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Large—Shared decision making in considering the benefits, harms, costs, and evaluation of the best treatment options. Clinicians should offer a comparison of evidence for the effectiveness of oral versus nasal administration of antihistamines and nasal steroids that will provide good patient adherence and treatment efficacy.

- Exclusions: None
- Policy level: Strong recommendation
- Differences of opinions: None

#### Statement 8. Intranasal Antihistamines

Clinicians may offer intranasal antihistamines for patients with seasonal, perennial, or episodic AR.

*Option based on RCTs with minor limitations and observational studies, with equilibrium of benefit and harm.*

##### *Action Statement Profile*

- Quality improvement opportunity: Improve awareness of this class of medications as another effective treatment for AR that may be an alternative to other medication classes
- Aggregate evidence quality: Grade A, based on RCTs with minor limitations and observational studies
- Level of confidence in evidence: High, but most of the trials were of short duration
- Benefits: Rapid onset, increased effectiveness over oral antihistamines for nasal congestion
- Risks, harms, costs: Increased cost relative to oral antihistamines, poor taste, sedation, more frequent dosing, epistaxis, local side effects
- Benefit-harm assessment: Equilibrium
- Value judgments: The Guideline Development Group felt that in general this class of medications would represent second-line therapy after failure of nasal steroids or oral antihistamines due to poor acceptance, taste, and cost but that there may be specific patients in whom this class would be an appropriate first-line therapy.
- Intentional vagueness: None
- Role of patient preferences: Large—There is equilibrium of benefits to risks when using intranasal antihistamine. Shared decision making may help ensure that the patient understands the potential benefits versus harms of undergoing this treatment, while also promoting patient compliance with medication.
- Exclusions: Not approved for children younger than 5 years
- Policy level: Option
- Differences of opinion: Minor; there are reasonable data supporting their use, but there was some debate regarding the harm-benefit ratio leading this to be an option. Several panel members thought these should be recommended at the same level as oral antihistamines.

#### Statement 9. Oral Leukotriene Receptor Antagonists (LTRAs)

Clinicians should not offer LTRAs as primary therapy for patients with AR.

*Recommendation against based on RCTs and systematic reviews, with a preponderance of benefit over harm.*

##### *Action Statement Profile*

- Quality improvement opportunity: Reduced use of a less effective agent for initial therapy
- Aggregate evidence quality: Grade A, based on RCTs and systematic reviews
- Level of confidence in evidence: High
- Benefits: Avoid ineffective or less effective therapy, cost saving, decreased variations in care
- Risks, harms, costs: There may be a subset of patients who would benefit from this medication (e.g., patients with both AR and asthma).
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: The panel was concerned with the cost of this medication in combination with the evidence that it is less effective than first-line medications.
- Intentional vagueness: None
- Role of patient preferences: Low—Rare patients with intolerance of intranasal therapy and concerns regarding somnolence may benefit from consideration of use of this class of medicine.
- Exclusions: Patient with concurrent diagnosis of asthma. These patients may benefit from oral LTRAs as a first-line therapy.
- Policy level: Recommendation
- Differences of opinion: None

#### Statement 10. Combination Therapy

Clinicians may offer combination pharmacologic therapy in patients with AR who have inadequate response to pharmacologic monotherapy.

*Option based on RCTs with minor limitations and observational studies, with equilibrium of benefit and harm.*

### *Action Statement Profile*

- Quality improvement opportunity: Reduce variations in care, improve symptom control
- Aggregate evidence quality: Grade A, based on RCTs with minor limitations and observational studies
- Level of confidence in evidence: High. There is strong evidence supporting the use of some combinations and the ineffectiveness of other combinations.
- Benefits: Improved effectiveness and symptom control of combined therapy
- Risks, harms, costs: Increased cost, overuse of medication, use of ineffective combinations, multiple medication side effects, drug interactions
- Benefit-harm assessment: Equilibrium
- Value judgments: None
- Intentional vagueness: The term "combination therapy" is nonspecific as there are multiple different combinations. The details are elaborated in the supporting text. The term "inadequate response to monotherapy" also allows for some interpretation by clinicians and patients.
- Role of patient preferences: Moderate—Shared decision making in consideration of evidence for benefits, harms and cost of combinations, effective dosing, and potential medication interactions to assist the patient in more effective treatment compliance.
- Exclusions: Decongestants that are part of some combined products are not approved for children under the age of 4 years.
- Policy level: Option
- Differences of opinion: None

### Statement 11. Immunotherapy

Clinicians should offer, or refer to a clinician who can offer, immunotherapy (sublingual or subcutaneous) for patients with AR who have inadequate response to symptoms with pharmacologic therapy with or without environmental controls.

*Recommendation based on RCTs and systematic reviews, with a preponderance of benefit over harm.*

### *Action Statement Profile*

- Opportunity for quality improvement: Increased appropriate use of immunotherapy and reduced variation in care; increased awareness of immunotherapy
- Aggregate evidence quality: Grade A, based on RCTs and systematic reviews
- Level of confidence in evidence: High
- Benefits: Altered natural history, improved symptom control, decreased need for medical therapy, long term cost-effectiveness, may improve or prevent asthma or other comorbidities, and may prevent new sensitizations
- Risks, harms, costs: Local reactions, systemic reactions including anaphylaxis, increased initial cost, frequency of treatment (logistics), pain of injection, delayed onset of symptom control (months)
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: The Guideline Development Group elected to use the term "inadequate response to medical therapy" as there are circumstances where immunotherapy may be beneficial for symptom control even if there is some response to medical therapy since immunotherapy addresses the underlying pathophysiology of atopy.
- Role of patient preferences: Large—There are potential risks, harms, and costs associated with the use of immunotherapy and a delayed onset. Shared decision making may help the patient understand the potential harms of undergoing this treatment. In addition, the efficacy of using this mode of therapy depends on patient compliance with frequency and duration of treatment as well as delay in onset of effect with immunotherapy.
- Exclusions: Uncontrolled asthma
- Policy Level: Recommendation
- Differences of opinion: Minor; some panel members felt that immunotherapy could be offered as first-line treatment to patients who elect not to use medical therapy.

### Statement 12. Inferior Turbinate Reduction

Clinicians may offer, or refer to a surgeon who can offer, inferior turbinate reduction in patients with AR with nasal airway obstruction and enlarged inferior turbinates who have failed medical management.

*Option based on observational studies, with a preponderance of benefit over harm.*

### *Action Statement Profile*

- Quality improvement opportunity: Improved nasal breathing and quality of life
- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in the evidence: Moderate
- Benefits: Improved symptoms, improved quality of life, improved medication delivery, reduced medication use, better sleep
- Risks, harms, costs: Unnecessary surgery, cost of surgery, risks of surgery, atrophic rhinitis
- Benefit-harm assessment: Balance of benefit and harm
- Value judgments: The panel felt that in spite of lack of head-to-head trials between medical and surgical therapy, surgery should be reserved for patients failing medical therapy due to the higher risk of any surgical management.
- Intentional vagueness: The panel elected to use the term "failure of medical therapy" as there are circumstances where inferior turbinate reduction may be beneficial for symptom control even if there is some response to medical therapy.
- Role of patient preferences: Large—Clinicians should use a shared decision-making process about the risks, benefits, and costs of undergoing surgery and associated use of anesthesia.
- Exclusions: Patients who are not surgical candidates
- Policy level: Option
- Differences of opinion: Minor difference of opinion whether AR is an independent risk factor for turbinate hypertrophy

#### Statement 13. Acupuncture

Clinicians may offer acupuncture, or refer to a clinician who can offer acupuncture, for patients with AR who are interested in nonpharmacologic therapy.

*Option based on RCTs with limitations, observational studies with consistent effects, and a preponderance of benefit over harm.*

#### Action Statement Profile

- Quality improvement opportunity: Increased awareness of acupuncture as a treatment option for AR
- Aggregate evidence quality: Grade B, based on RCTs with limitations, observational studies with consistent effects
- Level of confidence in evidence: Low; the randomized trials did not show comparison to traditional medical therapy for AR and had methodological flaws.
- Benefits: Effective alternative to medical therapies, reduction of symptoms, may more closely align with patient values, improved quality of life, avoidance of medication use and potential side effects
- Risks, harms, costs: Logistics of multiple treatments, need for multiple needle sticks, cost of treatment, rare infections
- Benefit-harm assessment: Equilibrium of benefit and harm
- Value judgments: Panel members varied in their preconceived bias for or against acupuncture.
- Intentional vagueness: None
- Role of patient preferences: Limited—Potential for shared decision making
- Exclusions: None
- Policy level: Option
- Differences of opinions: None

#### Statement 14. Herbal Therapy

No recommendation regarding the use of herbal therapy for patients with AR.

*No recommendation based on limited knowledge of herbal medicines and concern about the quality of standardization and safety.*

#### Action Statement Profile

- Quality improvement opportunity: Not applicable
- Aggregate evidence quality: Uncertain
- Level of confidence in evidence: Low. Many of the studies were small and of questionable methodology. The meta-analyses were done in English but looked at articles from the Chinese literature that are not available for assessment by the panel.
- Benefits: Improved awareness of alternative treatments, improved education of side effects of herbal therapy
- Risks, harms, costs: Not applicable
- Benefit-harm assessment: Not applicable
- Value judgments: There are many herbal therapies, but there is only evidence for a few that have appropriate studies. There is limited knowledge about these products among most of the panel members, and accordingly there was a bias against their use. There is concern about the quality of standardization of herbal medicines and their safety.

- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: No recommendation
- Differences of opinion: None

#### Definitions:

#### Evidence Quality for Grades of Evidence

Grade	Evidence Quality for Diagnosis	Evidence Quality for Treatment and Harm
<b>A</b>	Systematic review of cross-sectional studies with consistently applied reference standard and blinding	Well-designed randomized controlled trials performed on a population similar to the guideline's target population
<b>B</b>	Individual cross-sectional studies with consistently applied reference standard and blinding	Randomized controlled trials; overwhelmingly consistent evidence from observational studies
<b>C</b>	Nonconsecutive studies, case control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Observational studies (case control and cohort design)
<b>D</b>	Mechanism-based reasoning or case reports	
<b>X</b>	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm	

#### Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
<b>Strong Recommendation</b>	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B). In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
<b>Recommendation</b>	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C). In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
<b>Option</b>	An option means that either the quality of evidence that exists is suspect (grade D) or that well-done studies (grade A, B, or C) show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
<b>No Recommendation</b>	No recommendation means there is both a lack of pertinent evidence (grade D) and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

## Clinical Algorithm(s)

An algorithm titled "Allergic rhinitis (AR) diagnosis and treatment flow chart for evaluating and managing patients with AR based on this guideline's recommendations" is provided in the original guideline document.

# Scope

## Disease/Condition(s)

Allergic rhinitis (AR)

## Guideline Category

Diagnosis

Evaluation

Management

Treatment

## Clinical Specialty

Allergy and Immunology

Family Practice

Internal Medicine

Otolaryngology

Pediatrics

## Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To address quality improvement opportunities for all clinicians, in any setting, who are likely to manage patients with allergic rhinitis (AR) as well as to optimize patient care, promote effective diagnosis and therapy, and reduce harmful or unnecessary variations in care

## Target Population

Pediatric and adult patients with allergic rhinitis (AR)

Note: Children under the age of 2 years were excluded from the clinical practice guideline because rhinitis in this population may be different than in older patients and is not informed by the same evidence base.

## Interventions and Practices Considered

Diagnosis/Evaluation/Counseling

1. Patient history
2. Physical examination

3. Specific immunoglobulin E (IgE) (skin or blood) allergy testing
4. Sinonasal imaging (not recommended routinely)
5. Advising patients to avoid known allergens and to maintain environmental controls
6. Assessing for presence of chronic conditions and comorbidities

#### Treatment/Management

1. Intranasal steroids
2. Oral antihistamine
3. Intranasal antihistamines
4. Oral leukotriene receptor antagonists (LTRAs) (not recommended as primary therapy)
5. Combination therapy
6. Immunotherapy (sublingual or subcutaneous)
7. Inferior turbinate reduction
8. Acupuncture
9. Herbal therapy (no recommendation made)

## Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests
- Utility of diagnostic assessments in the evaluation for allergic rhinitis (AR)
- Effectiveness of environmental control measures for reducing symptoms of AR
- Association between comorbid conditions and AR
- Effectiveness of medications for improving symptoms of AR
- Adverse effects of AR medications and immunotherapy
- Effectiveness of immunotherapy for improving AR symptoms
- Effectiveness of inferior turbinate reduction for improving AR symptoms
- Effects of acupuncture on quality of life and avoidance of medication use and potential medication side effects

## Methodology

### Methods Used to Collect/Select the Evidence

#### Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

All literature searches were performed by an information specialist through May 2014.

An information specialist conducted 2 literature searches from June 2013 through November 2013, using a validated filter strategy, to identify clinical practice guidelines, systematic reviews, and randomized controlled trials (RCTs). The search terms used were ((Nasal Allergy[TW] OR Nasal Allergies[TW] OR Nose Allergy[TW] OR Pollinosis[TW] OR Pollinoses[TW] OR Catarrh[TW] OR Catarrhs[TW]) OR (Allergic Rhinitis[TW]) OR (((Rhinitis, Allergic, Perennial[MESH]) OR "Rhinitis, Allergic, Seasonal"[MESH]) OR "Rhinitis, Atrophic"[MESH]) AND ("1980/01/01"[PDAT]: "2013/12/31"[PDAT]) AND English[LANG])) AND ((Clinical Trial\*[PT] AND (Randomized[TW] OR Randomised[TW])) OR ("Randomized Controlled Trial"[PUBLICATION TYPE] OR Randomized Controlled Trial[TW] OR Randomized Controlled Trial[TW])). These search terms were used to capture all evidence on the population, incorporating all relevant treatments and outcomes.

The English-language searches were performed in multiple databases including the Cochrane Library, EMBASE, PubMed, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). In certain instances, targeted searches for lower level evidence were performed by panel members to address gaps from the systematic searches identified in writing the guideline from December 2013 through May 2014.

1. Clinical practice guidelines were identified by a PubMed search using guideline as a publication type or title word. The initial search

identified 54 guidelines. Articles were excluded if they (1) were not on the topic of the guideline, (2) were not available in English, (3) did not meet the panel's quality criteria (e.g., the review had a clear objective and method), (4) did not possess an explicit search strategy, and/or (5) did not have valid data extraction methods. After duplicates, irrelevant references, and non-English-language articles were removed, the final tally was 31 guidelines.

2. Systematic reviews were identified through EMBASE, the Cochrane Library, CINAHL, and PubMed. The initial data set included 759 systematic reviews or meta-analyses that were distributed to the panel members. Articles were excluded if they (1) were not on the topic of the guideline, (2) were not available in English, (3) did not meet the panel's quality criteria (e.g., the review had a clear objective and method), (4) did not possess an explicit search strategy, and/or (5) did not have valid data extraction methods. The final data set retained was 390 systematic reviews or meta-analyses.
3. The initial set of RCTs identified through PubMed, EMBASE, CINAHL, and the Cochrane Library totaled 2446 RCT articles. These were distributed among panel members for review. Articles were excluded if they (1) were unpublished RCTs, duplicate articles, and articles with unavailable abstracts (2) were not on the topic of the guideline, (3) were not available in English, (4) did not meet the panel's quality criteria (e.g., the review had a clear objective and method), (5) did not possess an explicit search strategy, and/or (6) did not have valid data extraction methods. The total final data set retained after the panel review was 1605 RCT articles.

## Number of Source Documents

The 31 clinical practice guidelines, 390 systematic reviews, and 1605 randomized controlled trials (RCTs) were broken down into the 14 key action statement categories. This material was supplemented, as needed, with targeted searches to address specific needs identified in writing the guideline through February 2014. After assessing quality and relevance, the guideline panel retained 9 of the clinical practice guidelines, 81 of the systematic reviews, and 177 of the RCTs.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

### Rating Scheme for the Strength of the Evidence

Evidence Quality for Grades of Evidence

Grade	Evidence Quality for Diagnosis	Evidence Quality for Treatment and Harm
<b>A</b>	Systematic review of cross-sectional studies with consistently applied reference standard and blinding	Well-designed randomized controlled trials performed on a population similar to the guideline's target population
<b>B</b>	Individual cross-sectional studies with consistently applied reference standard and blinding	Randomized controlled trials; overwhelmingly consistent evidence from observational studies
<b>C</b>	Nonconsecutive studies, case control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Observational studies (case control and cohort design)
<b>D</b>	Mechanism-based reasoning or case reports	
<b>X</b>	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm	

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined.

Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in the "Rating Scheme for the Strength of the Evidence" and the "Rating Scheme for the Strength of the Recommendations" fields. Because much of the guideline dealt with evidence relating to diagnostic tests, Evidence Quality for Grades of Evidence (see the "Rating Scheme for the Strength of the Evidence" field) was adapted to include current recommendations from the Oxford Centre for Evidence-Based Medicine.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

This guideline was developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. The Guideline Development Group consisted of 20 panel members representing experts in otolaryngology, allergy and immunology, internal medicine, family medicine, pediatrics, sleep medicine, advanced practice nursing, complementary and alternative medicine (acupuncture and herbal therapies), and consumer advocacy.

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During then 12 months devoted to guideline development ending in March 2014, the group met twice, with in-person meetings using electronic decision support (BRIDGE-Wiz, Yale Center for Medical Informatics, CT) software to facilitate creating actionable recommendations and evidence profiles. Internal electronic review and feedback on each guideline draft were used to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.

American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) staff used the Guideline Implementability Appraisal and Extractor (GLIA) to appraise adherence of the draft guideline to methodological standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. Guideline panel members received summary appraisals in April 2014 and modified an advanced draft of the guideline.

The recommendations contained in the guideline are based on the best available data published through May 2014. Where data were lacking, a combination of clinical experience and expert consensus was used.

## Rating Scheme for the Strength of the Recommendations

Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
<b>Strong Recommendation</b>	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B). <sup>*</sup> In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
<b>Recommendation</b>	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C). <sup>*</sup> In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
<b>Option</b>	An option means that either the quality of evidence that exists is suspect (grade D) <sup>*</sup> or that well-done studies (grade A, B, or C) <sup>*</sup> show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

No Statement Recommendation	Definition No recommendation means there is both a lack of pertinent evidence (grade D)* and an unclear balance between benefits and harms.	Implication Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

\*See the "Rating Scheme for the Strength of the Evidence" field for definitions of evidence grades.

## Cost Analysis

Recent literature suggests there may be a long-term cost savings with immunotherapy. The economic considerations regarding immunotherapy were evaluated, and evidence supports the cost-effectiveness of immunotherapy (subcutaneous immunotherapy [SCIT] and sublingual immunotherapy [SLIT]) compared with pharmacotherapy for allergic rhinitis (AR). A recent systematic review found a need for further research to determine the relative cost-effectiveness in comparing SCIT with SLIT; a 2012 US study found a wide variation of cost to the patient in regard to SCIT by insurance plan, and the cost of SLIT varied between practices 4-fold. While there are significant benefits of immunotherapy in AR, the decision to pursue immunotherapy should be based on shared decision making between the physician and the patient.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

The final guideline draft underwent extensive external peer review. Comments were compiled and reviewed by the panel's chair and co-chairs, and a modified version of the guideline was distributed and approved by the guideline development panel.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

The recommendations contained in the guideline are based on the best available data published through May 2014. Where data were lacking, a combination of clinical experience and expert consensus was used.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

This clinical practice guideline was undertaken to optimize the care of patients with allergic rhinitis (AR) by addressing quality improvement opportunities through an evaluation of the available evidence and an assessment of the harm-benefit balance of various diagnostic and management options.

For benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

## Potential Harms

- Inappropriate treatment and potential misdiagnosis from using history and physical alone
- Adverse events from testing, misinterpretation of results, and inaccurate test results (false positives and negatives)
- Potential erroneous diagnosis of chronic and comorbid conditions
- Tables 9, 10 and 11 in the original guideline document provide a list of the U.S. Food and Drug Administration (FDA)-approved intranasal steroids, oral antihistamines, and intranasal antihistamines for allergic rhinitis, including common side effects:
  - Topical steroids: topical side effects, epistaxis, drug side effects, potential growth concerns in children, septal perforation, and the cost of medication
  - Oral antihistamines: systemic side effects (sedation), dry eyes, urinary retention
  - Intranasal antihistamines: increased cost relative to oral antihistamines, poor taste, sedation, more frequent dosing, epistaxis, local side effects
  - Combination therapy: increased cost, overuse of medication, use of ineffective combinations, multiple medication side effects, drug interactions
- Local reactions, systemic reactions including anaphylaxis, pain of injection, and delayed onset of symptom control (months) with immunotherapy
- Unnecessary surgery, risks of surgery, and atrophic rhinitis with inferior turbinate reduction
- Rare infections from acupuncture

See the original guideline document for specific information on potential harms.

## Contraindications

### Contraindications

- Skin testing may be contraindicated when coexistent uncontrolled or severe asthma is present. Skin disease such as eczema can be a relative contraindication. Other contraindications may include coexisting medical conditions that would likely compromise survival should skin testing-induced anaphylaxis develop: for example, severe and unstable cardiovascular disease, concurrent use of  $\beta$ -blockers.
- The use of  $\beta$ -blockers is a relative contraindication to immunotherapy as this may complicate the treatment of anaphylaxis. The sublingual immunotherapy (SLIT) tablet is contraindicated in patients with severe, unstable, or uncontrolled asthma.
- Due to the potential for serious reactions, current practice guidelines indicate that subcutaneous immunotherapy (SCIT) should not be used in patients with uncontrolled asthma. The SLIT tablet is contraindicated in patients with severe, unstable, or uncontrolled asthma.
- Tables 9, 10 and 11 of the original guideline document provide a list of U.S. Food and Drug Administration (FDA)-approved intranasal steroids, oral antihistamines, and intranasal antihistamines for allergic rhinitis, including contraindications.

## Qualifying Statements

### Qualifying Statements

- The guideline is intended to focus on a limited number of quality improvement opportunities deemed most important by the working group and is not intended to be a comprehensive reference for diagnosing and managing allergic rhinitis (AR). The recommendations outlined in the guideline are not intended to represent the standard of care for patient management, nor are the recommendations intended to limit treatment or care provided to individual patients.
- Guidelines are not intended to supersede professional judgment but rather may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a "strong recommendation" than might be expected with a "recommendation." "Options" offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. Clinicians must also operate within their scope of practice and according to their training. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.
- Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline panel sought to minimize harm and diminish unnecessary and inappropriate therapy. A

major goal of the panel was to be transparent and explicit about how values were applied and to document the process.

- The clinical practice guideline is not intended as the sole source of guidance in managing patients with allergic rhinitis (AR). Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions but are not absolute. Guidelines are not mandates; these do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

## Implementation of the Guideline

### Description of Implementation Strategy

The clinical practice guideline is published as a supplement to *Otolaryngology—Head and Neck Surgery*, which will facilitate reference and distribution. A full-text version of the guideline will be accessible, free of charge, at <http://www.entnet.org> . In addition, all American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) guidelines are now available via the *Otolaryngology—Head and Neck Surgery* app for smartphones and tablets. The guideline will be presented to AAO-HNSF members as a mini seminar at the 2014 AAO-HNSF Annual Meeting and OTO EXPO. Existing brochures and publication by the AAO-HNSF will be updated to reflect the guideline's recommendations.

As a supplement to clinicians, an algorithm of the guideline's action statements and a table with common allergic rhinitis clinical scenarios has been provided. The algorithm allows for a more rapid understanding of the guideline's logic and the sequence of the action statements. The Guideline Development Group hopes the algorithm can be adopted as a quick reference guide to support the implementation of the guideline's recommendations.

### Implementation Tools

Clinical Algorithm

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

## IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

Seidman MD, Gurgel RK, Lin SY, Schwartz SR, Baroody FM, Bonner JR, Dawson DE, Dykewicz MS, Hackell JM, Han JK, Ishman SL, Krouse HJ, Malekzadeh S, Mirns JW, Omole FS, Reddy WD, Wallace DV, Walsh SA, Warren BE, Wilson MN, Nnacheta LC. Clinical practice guideline: allergic rhinitis. *Otolaryngol Head Neck Surg*. 2015 Feb;152(1 Suppl):S1-S43. [364 references] [PubMed](#)

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2015 Feb

### Guideline Developer(s)

American Academy of Otolaryngology - Head and Neck Surgery Foundation - Medical Specialty Society

### Source(s) of Funding

American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF)

### Guideline Committee

American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF) Guideline Development Panel

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## Financial Disclosures/Conflicts of Interest

### Financial Disclosure and Conflict of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF). Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call. After review and discussion of these disclosures, the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.

### Disclosures

*Competing interests:* Michael D. Seidman, medical director Scientific Advisory Board—Visalus, founder of Body Language Vitamin Co, National Institutes of Health grant on simulation, 6 patents but related to supplements, aircraft, and the middle ear and brain implant; Sandra Y. Lin, consultant for Wellpoint; Fuad M. Baroody, speaker for Merck, Inc, speaker for GlaxoSmithKline and speaker/consultant for Acclarent/Johnson/Johnson; Mark S. Dykewicz, consultant for Merck and research contract support to Saint Louis University for Novartis; Jesse M. Hackell, GlaxoSmithKline (Speakers Bureau), Sunovion Pharmaceuticals Inc. (Advisory Board) has had discussions regarding nasal corticosteroids, Transit of Venus (Advisory Board); Joseph K. Han, Medtronic research grant; PI and consultant on clinical study with Intersect, and speaker for Merck; Stacey L. Ishman, consultant for First Line Medical; Dana V. Wallace, TEVA (Speaker's Bureau), Sanofi (Advisory Panel and Speaker's Bureau), Mylan (Advisory Board and Speaker's Bureau), Sunovion (Speaker's Bureau), MEDA (Advisory Panel and Speaker's Bureau), ACAAI Executive Committee Chair and Board of Regents, Rhinitis/Sinusitis Committee, AAAAI/ACAAI/JCAAI Practice Parameter Joint Task Force.

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Electronic copies: Available from the [American Academy of Otolaryngology—Head and Neck Surgery Foundation \(AAO-HNSF\) Web site](#)

## Availability of Companion Documents

The following are available:

- Seidman MD, Gurgel RK, Lin SY, Schwartz SR, Baroody FM, Bonner JR, Dawson DE, Dykewicz MS, Hackell JM, Han JK, Ishman SL, Krouse HJ, Malekzadeh S, Mims JW, Omole FS, Reddy WD, Wallace DV, Walsh SA, Warren BE, Wilson MN, Nnacheta LC. Clinical practice guideline: allergic rhinitis executive summary. *Otolaryngol Head Neck Surg*. 2015 Feb;152(2):197-206. Electronic copies: Available from the [SAGE Journal Online Web site](#) .
- Clinical practice guideline: allergic rhinitis. Podcast Part 1 and 2. Alexandria (VA): American Academy of Otolaryngology – Head and

- Neck Surgery Foundation (AAO-HNSF). 2015 Feb. Available from the [AAO-HNSF Web site](#) .
- Clinical practice guideline: allergic rhinitis. Slide set. Alexandria (VA): American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF). 2015 Feb. Electronic copies: Available from the [AAO-HNSF Web site](#) .
  - Clinical practice guideline: allergic rhinitis. Pocket guide and mobile app. Alexandria (VA): American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF). 2015 Feb. Available from the [GuidelineCentral Web site](#) .

## Patient Resources

The following is available:

- Clinical practice guideline: allergic rhinitis. Plain language summary. Alexandria (VA): American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF). 2015 Feb. 2 p. Electronic copies: Available from the [AAO-HNSF Web site](#) .

In addition, a number of other patients resources related to allergies and hay fever and allergic rhinitis are available on the [AAO-HNSF Web site](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC Status

This NGC summary was completed by ECRI Institute on April 20, 2015. The information was verified by the guideline developer on April 30, 2015. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

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